The Alternatives to Animal Testing

You <u>can</u> do something to help stop the needless suffering of animals.

"Animal Testing—Cosmetics' Hidden Ingredient" and "Questions And Answers About Alternatives In Animal Research And Testing" Fact Sheets © 1994 by The Humane Society of the United States 2100 L Street, NW Washington, DC 20037, USA

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ANIMAL TESTING — COSMETICS' HIDDEN INGREDIENT

here is an unrecognised ingredient in most cosmetics, shampoos, soaps, toothpastes and other personal-care products. The ingredient is animal suffering. Each year, hundreds of thousands, if not millions, of rabbits, guinea pigs, mice, rates and other animals suffer or die in the safety testing of these products.

Such testing is not required by the federal government. And more and more companies are marketing products without resorting to animal testing. These progressive companies recognise that the tests not only cause animals to suffer, but also are unnecessary and, even when used, are of questionable relevance to public safety.

METHODS OF TESTING ON ANIMALS

The Draize Eye-Irritancy Test

The Draize Eye-Irritancy Test yields a rough estimate of how damaging a substance is to human eyes. In this test, substances are placed in the eyes of several restrained rabbits who then endure anything from mild redness and swelling to ulceration and haemorrhage of the eyeball. This test is a crude procedure and has little relevance to human safety. Many substances that are irritating to rabbit eyes are nonirritating to human eyes, and vice versa. Indeed, the Draize test has even yielded conflicting results when the same substances have been re-tested on more rabbits.

The LD50 Test

The Lethal Dose 50 per cent (LD50) test provides a rough measure of how poisonous a substance is to people by estimating the amount that is needed to kill 50 per cent of a group of test animals. In the most common variation of the LD50 test, dozens of animals are forced to ingest the test substance. In other variations, they are forced to breathe the test substance in a vapour, powder or spray, or they have the substance applied directly to their skin or injected into their bodies. Mice and rats are most commonly exploited in this test.

The LD50 test produces signs of poisoning such as bleeding from the eyes, nose or mouth, laboured breathing, convulsions, tremors, paralysis and coma. If the animals do not die by poisoning, they are killed at the end of the testing period which usually lasts two weeks.

The LD50 test is crude and nearly useless in protecting the public from unsafe products. The test's results vary so widely, depending on which species is used as the test subject, that predicting the human lethal dose on the basis of the LD50 test is nearly impossible. The test results are also affected by a test animal's age, sex and diet.

WHY IS COSMETICS TESTING ON ANIMALS UNJUSTIFIED?

Cosmetics are not life-saving drugs. Although animal testing of new drugs might be considered a necessary evil, animal testing of new cosmetics is an unnecessary evil. A civilised society should not condone animal suffering to have a new eyeshadow.

DON'T ANIMAL TESTS ASSURE HUMAN SAFETY?

No. Every year thousands of Americans injure themselves using products that had been tested on animals. There are several reasons for this. Products that have been judged harmless on the basis of animal tests can still be harmful to people. Furthermore, those products that have been judged harmful as a result of animal tests are not necessarily kept

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Blood harmlessly drawn from a horseshoe crab yields clumps of blood cells (in bottom of container to the left). The cells are the main ingredient of the LAL test, an *in vitro* alternative that screens intravenous fluids.

off the market. All that may be required for manufacturers to market such products is a warning label which can easily be overlooked by consumers.

Finally, when people are accidentally exposed to a hazardous substance, animal tests are largely irrelevant to mitigating injury because the tests are not designed to yield treatments for such injuries: they simply estimate the destruction that can be caused by a given substance.

AREN'T ANIMAL TESTS REQUIRED BY LAW?

No. The federal Food, Drug and Cosmetic Act does not require premarket testing of cosmetics and personal-care products. More and more manufacturers are ensuring the safety of their products by practising selective formulation—using only ingredients that are generally recognised as safe—and then performing carefully controlled studies using human volunteers. This approach is followed even by companies that test some of their products on animals. At least two companies have admitted that, based on existing safety information, some 70 to 90 per cent of their new products are not tested on animals.

NEW APPROACHES TO COSMETICS TESTING

Most of the cosmetic companies that use animals in safety testing do market some products that have not been tested on animals, but have refused to eliminate animal testing altogether. Many companies consider these tests their defence in the event that they are sued by consumers claiming to have been injured by unsafe products. Nevertheless, in one often-cited lawsuit, the judge ruled that the plaintiff failed to show that "the result of tests on rabbit eyes can be extrapolated to humans" and that the "rabbit studies, standing alone, do not warrant condemnation of this product" (despite injury to the rabbit).

The fear of lawsuits is only partially responsible for the continued use of animal testing. Another factor is the cosmetic industry's slow pace in developing and refining alternative testing methods. It therefore isn't surprising that the industry claims it needs more time to eliminate testing completely. Newer methods of safety testing fall into four categories:

Test-Tube Methods

Also known as in vitro methods, testtube procedures test the effects of substances on isolated cells, tissue fragments or organs. An advantage of these methods is that they allow researchers to test directly on human matter. The following two tests use human-eye tissue, which available from eye banks and eye research centres. The Clonetics Corporation (San Diego, CA) markets the Neutral Red Assay[™], an in vitro eye-irritation test. Neutral red is a dye that is readily absorbed by healthy, undamaged human cells; irritants impair the cell's capacity to absorb the dye. The degree of absorption impairment is a measure of irritancy potential.

Chemical Assays

In Vitro International (Irvine, CA) markets the EytexTM test, a chemical-test kit for estimating eye irritancy. The kit contains a mixture of chemicals that recreates key chemical components of the cornea. The test kit's chemicals, like those in the eye, turn cloudy in response to irritants. The degree of cloudiness is a measure of irritancy.

Tests on Nonsentient Organisms

Single-celled organisms and other animals with limited or no capacity for suffering are nevertheless sensitive to many irritating or poisonous substances. One of the most promising alternatives to the Draize Eye-Irritancy Test involves chicken embryos that have not yet developed to the point where they can feel pain but that have an outer membrane (within the shell) which responds to irritants. The membrane is exposed by cutting a small window in the shell. A plastic ring placed in the membrane serves as a well for the test substance. The degree of membrane response (cloudiness, inflammation and proliferation of blood vessels) is a measure of irritancy.

Computer Models

Computer models can help predict hazardous effects based on a substance's chemical and physical properties. The models rely on the information accumulated on already tested compounds to help predict the effects of untested compounds. Based on this principle, Health Designs, Inc. (Rochester, NY) has developed computer models that estimate LD50 values, Draize eye-irritancy scores and other test results.

Many alternative tests have been developed based on these approaches. Coupled with the process of selective formulation, these methods provide cosmetic companies with the tools necessary to market new products without resorting to animal testing. As a result of these technical breakthroughs, as well as considerable public pressure, several leading cosmetic companies have announced either a permanent end to their animal testing, or substantial progress in reducing their animal testing. While questions remain about some of these announcements and about the testing of ingredients (as distinct from the finished products), it is clear that the status quo of animal testing is changing.

Cosmetic companies that are unsatisfied with existing alternative testing methods should refine these methods. In the mean-

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Skintex solution reacts when mixed with a toxic substance. Such a test could replace the Draize skin test.

time, these companies should suspend animal testing and manufacture products only from the long list of ingredients already known to be safe.

Cosmetic companies that continue to test on animals should not hide behind technical arguments about the shortcomings of existing non-animal test methods. In the event that the industry is never completely satisfied with alternative methods and continues to rely on animals to a certain extent, the HSUS would continue to object to the painful testing of cosmetics on animals on the grounds that it is both unethical and powerless to assure human safety.

WHAT ARE SOME SCIENTIFIC DISADVANTAGES OF TRADITIONAL ANIMAL RESEARCH AND TESTING?

Animals and humans differ in medically important ways. Therefore effects of drugs and other treatments studied in animals are not necessarily seen in humans, and many effects that do occur in humans have no apparent counterparts or are not readily observable in animals (for example, nausea or headache).

Animal 'models' of human diseases involve artificially inducing injury or disease in other species. To what extent do the resulting disorders resemble naturally occurring human disorders? It is difficult to know. According to a researcher at the National Institutes of Health (NIH), himself an advocate of animal models, "in virtually no case is an animal model a perfect...replica of the human disorder under study. Rather, it is usually a highly simplified, theoretically biased, and incompletely generalised version."

Many animal tests are widely regarded as outmoded. The Lethal Dose 50 per cent (LD50) test, which estimates the dose of a substance necessary to kill half the test animals, has been termed "an anachronism" by the former director of the National Toxicology Program.

WHAT ARE SOME EXAMPLES OF THE ADVANTAGES AND IMPORTANCE OF REPLACEMENT ALTERNATIVES?

A review of all Nobel Prizes awarded in physiology or medicine through 1985 revealed the strong role of alternatives in research that the National Academy of Sciences (NAS) has described as "of the highest calibre, the most enduring influence, and the most importance to biomedical science". Two-thirds of the prizes were awarded to research that included major contributions from alternative techniques.

The National Cancer Institute has replaced the use of mice with a technologically advanced in vitro system to determine the anticancer properties of potential drugs. The new system can screen the effects of about 20,000 compounds on several human cancer cell types for approximately the same cost as testing the compounds' effects on only one cancer type in mice. The number of mice used in the mouse testing, now reserved for secondary testing only, has dropped from a peak of six million animals annually to 300,000.

Alternative methods can answer questions that traditional animal studies cannot. According to the NAS, "major recent advances in our knowledge of the immune system made possible by cell cultures would have been virtually impossible to achieve in intact vertebrates."

WHAT ARE SOME SPECIFIC EXAMPLES OF REDUCTION AND REFINEMENT?

In the standard Draize eye-irritancy test, intended to assess how damaging substances might be to human eyes, at least six rabbits receive a relatively large dose of a chemical ion one eye. US regulatory agencies are considering modifications that would reduce the amount of suffering involved. One reduction under consideration is to use from one to three rabbits, instead of the usual six. In many instances, the smaller number can provide nearly the same information as the standard number. One refinement under consideration is to treat the rabbits' eyes with an anaesthetic before adding the potentially irritating chemical.

In the classical LD50 test, researchers attempting to obtain a rough measure of a substance's toxicity deliberately poison scores of animals to estimate the dose that kills half of the animals. Several reduction alternatives using 10 to 20 animals, includ-



A new, high-tech device measures toxicity using microscopic wells in a silicon chip (left), to which human cells are adhered (right).

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ing the Approximate Lethal Dose and the Up and Down Method, have rendered the classical method obsolete. Other modifications of the classical method are refinement alternatives as well as reduction alternatives. The Fixed Dose Procedure and the Limit Test involve fewer animals and, because they avoid poisoning animals to death, lessen any resulting pain and suffering.

WHAT ARE SOME SIGNS THAT ALTERNATIVES ARE STARTING TO BE TAKEN SERIOUSLY?

In the USA, Animal Welfare Act amendments enacted in 1985 mandate (a) the creation of an information service to promote alternative methods, (b) training in alternative methods for laboratory workers, and (c) a review of proposed animal experiments to ensure that the principles of the three Rs are being applied.

The Health Research Extension Act, passed in 1985, requires the NIH, the federal government's largest funding source for biomedical research, to promote alternative methods. The NIH has implemented a special program, albeit modest, that funds research based on alternatives.

In 1986 the Congressional Office of

Technology Assessment released a landmark 441-page report, "Alternatives to Animal Use in Research, Testing and Education".

Corporations and trade associations are increasingly supporting alternatives research in-house and at such institutions as the Johns Hopkins Center for Alternatives to Animal Testing. Several major corporations, including Avon and Revlon, have completely replaced animal testing of their products with alternative methods.

WHAT NEEDS TO BE DONE?

Manufacturers, regulatory agencies and testing companies should endorse the three-Rs approach, aid the development of alternative testing methods, and implement these methods whenever possible.

Public and private organisations that fund research should endorse the three Rs, fund research that employs alternatives, and underwrite research aimed at developing alternative methods.

Consumers and investors should 'vote with their pocketbooks' by buying from companies that embrace the three Rs.

A list of cosmetic companies that market products not tested on animals is available from any of the following groups. ∞

Australia:

Humane Society International, Inc., Australia

PO Box 302, Avalon, NSW 2107 Phone: (02) 973 1728 Fax: (02) 973 1729

Campaign Against Fraudulent Medical Research

PO Box 234, Lawson, NSW 2783 Phone/Fax: (047) 58 6822

Guardians—A Group Exposing Vivisection PO Box 59, Pascoe Vale South, Vic 3044 Phone: (03) 386 3778 Fax: (03) 386 3778 Hotline: 0055 10575

<u>USA</u>:

The Humane Society of the United States 2100 L Street, NW, Washington, DC 20037 Phone: (202) 452 1100